

### REMARKS

In the accompanying amendment, claims 1, 4 and 10-11 have been amended, and claim 2-3 have been cancelled. The amendment to claims is supported by the original filed specification, claims, and drawings. On account of the foregoing listed support for the amendments to claim 1, it is respectfully submitted that the amendment to claim 1 does not add new matter.

#### Claim Rejections under 35 USC §102

Claims 1, 4-5, 7 and 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Visser et al. (WO 98/56325) (pub. Dec. 17, 1998).

Claim 1 as amended, includes the following limitations:

A patch device adapted for use in the transdermal administration to a patient of a composition including, or consisting of, dimethylformamide (DMF), the patch consisting of a layered construct adapted to be adhered to the skin of a patient and defining a depot cavity for the composition to be administered between a proximal layer and a distal layer thereof, which proximal layer is adapted in use to be located in intimate contact with the skin of the patient and which distal layer is in use disposed on the outer side thereof, the distal layer being characterized in that it comprises a composite layer having a first layer which is flexible and made of an elastomeric silicone material which is partially permeable to the composition to be administered; and a second layer which is impervious to said composition, and the proximal layer being characterized in that it is flexible and made of said elastomeric silicone material and is partially permeable to the composition, so that in use the composition may be disposed in the cavity and permeates from there through the proximal layer to be absorbed through the skin into the body of the patient, the proximal and distal layers being bonded to portions of each other by means of silicone adhesive or by vulcanizing, the proximal layer being further characterized in that its permeability to the irritating substance or component of the composition to be administered to the human or animal is less than the permeability of the human or animal skin, as the case may be, to such irritating substance or component.

(Claim 1, underling for emphasis),

Applicant respectfully submits that Visser et al does not teach or suggest a distal layer comprising a composite layer having a first layer which is flexible and made of an elastomeric

silicon material which is partially permeable to the composition to be administered; and a second layer which is impervious to said composition.

Thus, Visser et al does not teach or suggest all limitations of claim 1. Accordingly, it is respectfully submitted that claim 1 is not anticipated or rendered obvious by Visser et al.

Given that claims 4-11 depend on claim 1, it is respectfully submitted that these claims are also not anticipated or rendered obvious by Visser et al.

#### Claim Rejection Under 35 USC §103

Claims 1-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Visser et al. (WO 98/56325) (pub, Dec, 17, 1998) in view of Landauer et al. (WO 99/13885) (pub, Mar, 25, 1999),

Landuer et al discloses varying the density of the proximal and distal layers to control the flow of the drug through the proximal layer to the patient's skin. This function is achieved by the composite distal layer recited in Claim 1. Such a composite distal layer is not taught or suggested by Visser et al and Landuer either in combination or whether considered individually. Thus, it is respectfully submitted that the combination of Visser et al and Landuer does not teach or suggest all limitations of claims 1-11 and therefore cannot render these claims obvious, as suggested by the Examiner.

Accordingly the Examiner is respectfully requested to withdraw the rejection of claims 1-11 in view of the combination of Visser et al and Landuer.

With regard to claims 12 and 13, the combinations of prior art references proposed by the Examiner in rejecting these claims under 35 USC §103 does not teach or suggest the above-discussed limitations. Thus, it is respectfully submitted that claims 12 and 13 are not rendered obvious by the proposed combinations of references suggested by the examiner. Accordingly, the

Examiner is respectfully requested to withdraw the rejection of claims 12 and 13 under 35 USC §103.

Conclusion

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney (650) 7965417 to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 503437.

Respectfully submitted,

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